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FOOD PRODUCTS ASSOCIATION

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October 17, 2005

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Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm 1061
Rockville, MD 20852

RE: Docket No. 2005N-0349; Agency Information Collection Activities: Proposed Collection; Comment Request; Food and Drug Administration Survey of Current Manufacturing Practices in the Food Industry; 70 Federal Register 54390; September 14, 2005

Dear Sir or Madam:

The Food Products Association (FPA) (formerly National Food Processors Association) is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. FPA's scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. FPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

The referenced FDA notice solicits comments on a proposed Internet survey of current manufacturing practices in the food industry. The stated purpose is to improve FDA's understanding of current food industry manufacturing practices. Selected respondents from the survey will be approached for additional information.

Much of the information FDA seeks is proprietary. Firms will be reluctant to share this information without assurance that individual company data will not be accessible to FDA staff nor to any third party. In the notice (70 FR 54390 at 54391), the agency states that

> "Under its contract with FDA, ERG is precluded from releasing to the public any study data or findings without FDA's prior approval." (Emphasis added)

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This suggests that individual company data could be made available to the public with FDA's approval (for example, FDA's response to a request for this information under the Freedom of Information Act (FOIA)).

The information collection form should either include assurances that individual company information is not subject to release under the Freedom of Information Act (FOIA) or alert the company official to the fact that this information is or may be subject to FOIA. FPA requests that FDA legal counsel provide information on how this data will be considered with respect to FOIA and the FDA regulations under 21 CFR §20. If the data is or may be subject to FOIA, this fact should be revealed to the respondents and information on how to protect proprietary information should be provided.

FPA also requests that information on how data will be handled upon completion of the project (retention period, date and method of destruction of raw data) be shared.

In order to maintain confidentiality, FPA believes that no company names, respondents or non-respondents should be provided to FDA by the contractor. A generic summary of the response rate should be adequate for FDA purposes.

Also to maintain confidentiality, FPA urges that ERG staff make the selection of companies for follow-up interviews based on predetermined FDA criteria.

FDA asserts that the survey will be sent to every FDA-registered facility in the United States, Japan, Canada, China, France, Italy and Mexico that are primarily manufactures of processed food products and that included an e-mail address with their registration. By this, FPA presumes that only one contact will be made with each individual firm through the main firm contact listed on the firm's facility registration form and not to each location where the firm has a production facility. FPA believes that each firm should receive only one solicitation for information that is made directly to the individual listed as the firm's designated official contact. Likewise, contact with firms located outside the United States should be made through their designated U.S. representative.

Finally, the survey request should state clearly that participation in the survey is entirely voluntary and that non-participation will not affect the company's regulatory status in any way and that FDA will have no means of knowing whether the company participated in the survey.

Thank you for providing this opportunity to comment on the proposed survey.

Sincerely,

Allen Matthys, Ph.D.
Vice President, Federal and State Regulations